JUL 1 1 2001

K011987

Section 5.0 Safety and Effectiveness 510(k) Summary

1. The Modified M-IV Mammography Systems have been designed for classification to Underwriters Laboratories, Inc. (UL) to Standard 187.

2. The Modified M-IV Mammography Systems have been designed for classification by Underwriters Laboratories, Inc. to Canadian Standards Association, CSA Standard C22.2 No.114.

3. The Modified M-IV Mammography Systems have been designed for certification to International Electrotechnical Commission Standard IEC-601-1

4. The Modified M-IV Mammography Systems are tested and conform to the Federal Performance Standards for Ionizing Radiation Emitting Products, defined in 21CFR 1000.

5. The American College of Radiology (ACR) in Reston, Virginia, conducts a nationwide program that accredits providers of mammography services. To qualify for ACR accreditation, the mammography device at a provider site must meet ACR standards for image quality and operation within radiation dose limits. The Modified M-IV Mammography Systems have been designed to meet the requirements for ACR accreditation.

6. A comprehensive Operator's Manual provided with each system is user friendly and comprehensive, thus ensuring safe and effective operation of the Modified M-IV Mammography Systems.

This information is provided pursuant to the requirements of the Safe Medical Devices Act of 1990 (SMDA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2001

Mr. Roaida Rizkallah
Regulatory Specialist
Lorad, A Hologic Company
36 Apple Ridge Road
DANBURY CT 06810

Re: K011987
Modified M-IV Mammography System
Dated: June 22, 2001
Received: June 26, 2001
Regulatory Class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Rizkallah:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):

Device Name: Modified M-IV Mammography System

Intended Use:

The Modified M-IV Mammography System is intended to produce radiographic images of the breast. Its specific intended use is for screening and diagnostic mammography. Screening mammography involves the production of images for initial examination for breast cancer diagnosis. Diagnostic mammography includes the production of magnified images for more thorough examination of areas of the breast determined suspicious through screening mammography, special views, spot compression views, and the production of images used by a physician in preparation for biopsy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___
21 CFR 801.109

David C. Segroves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011987